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Total Number of Pages in This Submission

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|------------------------|-------------------|
| Application Number | 09/808,314 |
| Filing Date | March 14, 2001 |
| First Named Inventor | Randall W. Nelson |
| Art Unit | 1641 |
| Examiner Name | Gary W. Counts |
| Attorney Docket Number | 41821.0238 |

ENCLOSURES (Check all that apply)

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June 11, 2007

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Randall W. Nelson et al.
Serial No.: 09/808,314
Filing Date: March 14, 2001
Title: MASS SPECTROMETRIC IMMUNOASSAY
Examiner: Gary W. Counts
Art Unit: 1641

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**APPELLANT'S REPLY BRIEF
PURSUANT TO 37 C.F.R. § 31.41(a)(1)**

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(Submitted in Triplicate)

I. STATUS OF CLAIMS

Claims 31-33, 35-40, 42, 44-46, and 48 are pending in the application.

Claims 31-33, 35-40, 42, 44-46, and 48 stand rejected under 35 U.S.C. §103(a) and are appealed herein.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 31-33, 35 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Papac et al. (Direct Analysis of Affinity-Bound Analytes by MALDI/TOF, Anal. Chem. 1994, 66, 2609-2613) in view of Gaskell (Quantification of Steroid Conjugates Using Fast Atom Bombardment Mass Spectrometry, Steroids, 1990, Vol. 55, pp. 458-462).

Claims 37-40 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Papac et al. in view of Gaskell as applied to claims 31-33, 35 and 36 above, and further in view of Chiabrando et al. (Journal of Chromatography 495 (1989) 1-11).

Claims 44-46 and 48 under 35 U.S.C. § 103(a) as being unpatentable over Papac et al. and Gaskell in view of Chiabrando et al. as applied to claims 31-33, 35-40 and 42 above, and further in view of Merren, U.S. Patent No. 3,770,337.

III. ARGUMENT

This Reply Brief is in response to the Examiner's Answer mailed on April 11, 2007. Pursuant to 37 C.F.R. §31.41(a)(1), Appellant may file a Reply Brief to an Examiner's Answer. Accordingly, Appellant is filing this Reply Brief which addresses the points of argument set out by the Examiner in the Examiner's Answer. **This Reply Brief is being submitted in triplicate.**

A. Claims 31-33, 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Papac et al in view of Gaskell (see Examiner's Answer, page 4). In response to Appellant's arguments, the Examiner specifically stated that "The Examiner has not relied upon Papac for determining the amount but rather has relied upon Gaskell for teaching that it is known in the art to use internal reference species in mass spectrometry assays and teaches that this provides for precise and accurate data for quantification of analytes. (See Examiner's Answer, page 8). The Examiner also specifically stated that the Examiner "agrees that Papac does not teach quantification (see the 103 rejection above)" (see Examiner's Answer, page 10).

The Examiner further states the following: "However, Gaskell teaches that it is known in the art to use internal reference species in mass spectrometry assays and teaches that this provides for precise and accurate data for quantification of analytes."

Appellant argues that the Gaskell reference actually teaches away from Appellant's claimed invention with respect to Appellant's quantifying step contained in its claims because Gaskell uses tandem MS for quantification. In Gaskell, different mass spectrometric measurements were taken of similar portions of the same serum extract and compared. In contrast, in Appellant's instantly claimed invention, the analyte and internal reference species (IRS) are measured using MS in a single measurement, in other words single dimension mass spectrometry. The Examiner states that he does not find this argument persuasive because "As stated in the previous office actions the Examiner has not relied upon Gaskell for teaching tandem MS, but rather has relied upon Gaskell for teaching that it is known in the art to incorporate internal references into a sample for the quantification of an analyte." The Examiner further states that "The primary reference (Papac et al) clearly teaches the use of MALDI/TOF (single dimension) (same as used by Applicant) in a method for the detection of analyte and the secondary reference (Gaskell) teaches the incorporation of an internal standard and methods to provide for the quantification of an analyte." (See Examiner's Answer, page 11). The Examiner further states that he "has not relied upon Gaskell for the steps of quantification but rather has relied upon Gaskell for teaching that it is known in the art to use internal standards to develop a standard curve which provides for the quantification of an analyte." The Examiner then states that one of ordinary skill in the art would understand that the incorporation of a standard curve of Gaskell in the method of Papac provides for the quantification of an analyte and that "the combination of Papac et al and Gaskell would include a single dimension mass spectrometric process for quantifying an analyte." (See Examiner's Answer, pages 11-12).

Appellant respectfully traverse the Examiner's argument in that Appellant's amended claims specifically include the step of "quantifying the at least one of the one or more analytes in which said quantifying step comprises using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS to determine the amount of the captured analyte relative to the IRS." As previously stated above, Gaskell fails to teach quantification using only single dimension mass spectrometric analysis. In addition, the Examiner has stated that he has relied on neither Papac nor Gaskell for teaching the step of quantification. Therefore,

in that the Examiner has confirmed that neither Papac nor Gaskell teaches Appellant's claimed step of quantifying using only single dimension mass spectrometric analysis, it would not be obvious to one of ordinary skill in the art to combine Papac and Gaskell to arrive at Appellant's claimed invention.

B. Claims 37-40 and 42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Papac et al in view of Gaskell as applied to claims 31-33, 35 and 36 above, and further in view of Chiabrando et al. (See Examiner's Answer, page 6). Appellant has argued that Chiabrando discloses a method which utilizes gas chromatography-mass spectrometry and that Chiabrando fails to disclose the use of single dimension mass spectrometry to analyze and quantify an analyte. In response to Appellant's argument, the Examiner states that Appellant's argument is not found persuasive because "The Examiner has not relied upon Chiabrando for teaching these limitations but rather has relied upon Papac and Gaskell for teaching these limitations." The Examiner further states that he "has relied upon Chiabrando for teaching that it is known in the art to combine a plurality of distinctive internal reference species to a sample." (See Examiner's Answer, page 12).

As previously explained above, neither Papac or Gaskell disclose Appellant's claim step of quantifying using only single dimension mass spectrometric analysis. In addition, in that the Examiner has stated that he has not relied on Chiabrando for teaching this step, it would not be obvious to one of ordinary skill in the art to combine Papac, Gaskell, and Chiabrando to arrive at Appellant's claims.

C. Claims 44-46 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Papac et al and Gaskell in view of Chiabrando et al as applied to claims 31-33, 35-40 and 42 above, and further in view of Merren. Appellant previously argued that Merren fails to disclose single dimension mass spectrometric analysis of an analyte and an internal reference species using a standard single beam mass spectrometer. Instead, Merren discloses a double beam mass spectrometer for simultaneously enabling mass spectral analysis for two substances such as an unknown and a reference substance. Merren also fails to disclose quantifying one or more analytes using only single dimension mass spectrometric analysis. The Examiner finds Appellant's arguments to be unpersuasive because the Examiner "has not relied upon Merren for teaching single dimension mass spectrometric analysis but rather has relied upon the combination of Papac, Gaskell and Chiabrando for teaching this limitation." The

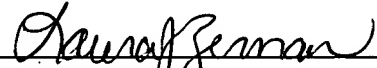
Examiner further states that he "has relied upon Merren for teaching interpolating the analyte species' mass spectrometric response to the IRS's mass spectrometric response." (See Examiner's Answer, page 13).

As previously explained above, neither Papac, Gaskell, or Chiabrando teach the limitation of quantifying one or more analytes using only single dimension mass spectrometric analysis. In addition, the Examiner has stated that he has not relied upon Merren for teaching the same limitation. Therefore, it could not be obvious to one of ordinary skill in the art to combine Papac, Gaskell, Chiabrando, and Merren to arrive at Appellant's claimed invention.

For the above reasons, as well as all of those arguments set out in previous papers contained in the record, Appellant contends that Appellant's pending patent claims are directed to patentable subject matter.

Dated: 6/11/07

Respectfully submitted,

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